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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,373	05/16/2001	Robert P. Kimberly	UAB-14202/22	5348

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Ellen S Cogen  
Gifford Krass Groh Sprinkle Anderson & Citkowski  
Suite 400  
280 N Old Woodward Avenue  
Birmingham, MI 48009-5394

EXAMINER

SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/744,373

Applicant(s)

KIMBERLY, ROBERT P.

Examiner

Sally A Sakelaris

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See continuation sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-21, 26-30 and 36-46.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
JEFFREY FREDMAN  
PRIMARY EXAMINER

Continuation of 2. NOTE: The proposed amendments extensively modifies the claims and as a result will not be entered. The recitation of "a cell expressing FcαRI" and "for FcαRI alleles selected from the group consisting of: FcαRIa 87R/87R, FcαRIa 92D/92N, FcαRIa 132F/132L, FcαRI 245P/245L and FcαRI 248S/248G" raises issues under 112 1st paragraph enablement and include new limitations that require a new and revised search of the prior art.

Continuation of 5. does NOT place the application in condition for allowance because: the applicant's traversal on the grounds that first, the Chee et al. reference is "incapable of performing the functions of pending claim 34" is acknowledged but the examiner maintains her position that the reference does anticipate these claims' recitation of the intended use that does not result in a structural difference between the claimed invention and the prior art. Applicant should note that in fact the Chee et al. reference does anticipate claim 34 as the claim as presently written does not require the identification of the specific SNP in a FcαRI genotype or phenotype (See Pg 3 of final rejection for complete reasoning). With respect to the arguments concerning the maintained rejection under 35 U.S.C. 112, first paragraph, the examiner acknowledges applicant's submission that they assert; that the in re Wands factors are satisfied by the instant specification, that with a finding of enablement for each and every element of the claimed invention the resulting invention is enabled, and further that they assert that "it is not necessary that a court review all the Wands factors to find a disclosure enabling. These arguments are not found to be convincing. The examiner acknowledges that while a whole method may be not enabled, its constitutive steps may. For example, a method that is drawn to a cure for all cancers that comprises the detection of SNPs is clearly not enabled whilst the single method step of SNP detection is clearly enabled by both prior and post date art and one of ordinary skill in the art. As a result, the examiner finds applicants arguments on pages 11-12 to be unconvincing. On page 11 applicant analyzes each method step and points the examiner to the relevant lines within the specification that allegedly enable each step. Applicant's analysis of the method steps is acknowledged, however, the enablement for the method as claimed, ie the correlation of the ability of a cell expressing FcαRI to bind IgA and cellular susceptibility to a disease cannot be found by analyzing each step individually since while each step may be enabled, the method in its entirety is not. Additionally, applicants point examiner (on page 12) to references 45-50 that "explicitly identify a role if IgA binding affinity in periodontal disease. Even if arguendo, these references teach "a role of IgA binding affinity in periodontal disease", the references still lack a teaching that is capable of enabling the claims as broadly as they are presently written. Applicant should note that while method steps including the detection of SNPs is enabled, the use of these SNPs is not. While applicant points to page 11 in their specification to provide the examiner with the "how to use" basis for the enablement requirement, the examiner does not find this citation to be convincing. The specification lacks a teaching of how to use the FcαRI genotype in any correlation to disease. Applicant's further citation of the specification at pages 6 and 7 points examiner to data involving FcγRI and IgG. Applicant is reminded of the unequivalence established between these two molecules and those that are claimed in the prior final action. As a result, applicants arguments concerning the availability of understanding relating to how the IgA binding relates to cell genotype and therefore to disease to be unconvincing. In response to applicant's comments regarding basic immunology, as stated above just because a part of an invention or a method step is enabled by the art does not mean that the entire invention encompassing some of these enabled steps is enabled. Applicant should also note that the citation of case law in this response does not appear to make sense to the examiner. Lastly, the applicant's interpretation of the In re Wands factors is noted. However, the examiner does not find this interpretation to be convincing as she maintains the enablement analysis constructed in her previous two actions sent to applicant. In summary, as stated in the Final action, dated October 07, 2003, the examiner finds the remaining traversals not convincing as it is maintained that the present method lacks enablement as previously prescribed. Furthermore, the remaining rejections are also maintained for reasons of record in view of the non-entry of after final amendment.

*Jelly Sah*  
1/15/2004